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UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF TEXAS

EL PASO DIVISION

LEANNE SPARLING and MICHAEL J SPARLING, on behalf of and as representatives for MICHAEL L SPARLING, deceased, Plaintiffs, v. USPLABS, LLC, JONATHAN VINCENT DOYLE (an individual), JACOB GEISSLER (an individual), USPLABS JACK3D, LLC, USPLABS HOLDING, LLC, GNC CORPORATION, and DOES 1-500, Inclusive, Defendants.	No. EP-13-CV-00323-DCG **FIRST AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL** 1. Negligence 2. Strict Products Liability – Defective Design 3. Strict Products Liability – Failure to Warn 4. Breach of Express Warranty 5. Breach of Implied Warranty 6. Punitive Damages 7. Wrongful Death 8. Survival

Plaintiffs LEANNE SPARLING and MICHAEL J SPARLING, on behalf of and as successors/representatives for MICHAEL L SPARLING, deceased, by and through their Attorneys of record, bring this action against Defendants USPLABS, LLC, JONATHAN VINCENT DOYLE (an individual), JACOB GEISSLER (an individual), USPLABS JACK3D, LLC, USPLABS HOLDING, LLC, GNC CORPORATION, and DOES 1-500, (collectively, "DEFENDANTS"). Plaintiffs allege on information and belief, except for information based on personal knowledge, as follows:

JURISDICTION AND VENUE

1. Plaintiffs allege an amount in controversy in excess of the minimal jurisdictional limits of this Court.

2. Venue is proper since Plaintiffs allege that the events in question took place on Fort Bliss, a military base within the greater boundaries of the state of Texas.

DEFENDANT PARTIES

I. Product Marketers

3. Defendants USPLABS, LLC, USPLABS JACK3D, LLC, and USPLABS HOLDING, LLC are Wyoming corporations (except as to USPLABS, LLC which is a Texas corporation) headquartered in Dallas, TX and were and are regularly engaged in the business of licensing, manufacturing, formulating, packaging, distributing, and/or selling, either directly or indirectly, through third parties or related entities, non-prescription dietary supplements for sale to, and use by, members of the general public, and as a part of their business, said Defendants, directly or indirectly were and are engaged in the manufacturing/formulating/packaging/distributing/selling of a purported nutritional/dietary supplement under the proprietary, trademarked name "Jack3d" in interstate commerce and in Texas, which Plaintiff-Decedent ingested as alleged herein.

4. Jack3d contains the ingredient 1,3-dimethylamylamine (also known as, and hereinafter referred to, as "DMAA"), a dangerous sympathomimetic, which can cause adverse cardiovascular events such as heart attack, stroke, heart arrhythmias, heart palpitations, dizziness, cardiac arrest, rhabdomyolysis, loss of consciousness and death.

5. Defendants JONATHAN VINCENT DOYLE and JACOB GEISSLER, who live in Denton, TX, are individuals having ownership interest in and executive positions in the USP entities. Upon information and belief, Defendants DOYLE and GEISSLER are shareholders in each of the USP entities, are corporate officers in each of the USP entities, direct and participate in the day to day operations of the USP entities, were responsible for the acts of the USP entities and for all intents and purposes own, operate and act through the USP entities. (USPLABS, LLC, JONATHAN VINCENT DOYLE (an individual), JACOB GEISSLER (an individual), USPLABS JACK3D, LLC, and USPLABS HOLDING, LLC, are hereinafter collectively referred to as "USP" or "USP DEFENDANTS".)

6. Furthermore, USP DEFENDANTS were at all times alleged herein under the control of their founders and dominant principals, Defendants JONATHAN VINCENT DOYLE and JACOB GEISSLER. The Corporate filing for USPLabs, LLC with the Texas Secretary of State states "The limited liability company is to be managed by managers, the names and addresses of the governing persons are set forth below" wherein GEISSLER and DOYLE are named.

7. At all times herein alleged, each of the acts of the employees, including but not limited to Defendants DOYLE and GEISSLER, were on behalf of, for the benefit of, at the direction of, and at the behest of USP DEFENDANTS and were ratified by said USP DEFENDANTS. Further, each of the acts of the employees, including but not limited to Defendants DOYLE and GEISSLER were done pursuant to and in accordance with corporate policy.

8. USP DEFENDANTS, and each of them, are engaged in a single enterprise of developing, marketing, and distributing dietary supplements. There exists, and at all times herein alleged, there existed, a unity of interest in ownership between and among USP DEFENDANTS such that any individuality and separateness between and among USP DEFENDANTS has ceased and the individual USP DEFENDANTS are the alter-egos of and agents of each other and exerted control over each other. Adherence to the fiction of the separate existence of the USP DEFENDANTS as entities distinct from each other will permit an abuse of the corporate privilege and would sanction fraud and promote injustice. The alter ego entities were formed for the purpose

of selling untested and dangerous dietary supplements, including Jack3d, which carried a high risk of causing serious personal injuries, without being responsible to the injured customers. Specifically,

I. Identical Ownership and Concealment of Responsible Entities

9. At all times, Defendants Geissler and Doyle, acting through the parent Defendant USPLabs, LLC, owned and controlled both the Jack3d trademark and the Defendant USPLABS JACK3D, LLC entity:

- In 2010, USPLABS, LLC, the parent entity, initially registered for the trademark "USPLABS Jack3d."

- Defendants Geissler and Doyle founded, manage and govern "USPLABS, LLC" and were therefore in control of the "USPLabs Jack3d" trademark in 2010.

- Subsequently, in 2012, an additional JACK3D trademark, namely "Jack3d" was registered to USPLABS JACK3D, LLC.

At the time of its corporate founding, JACK3D, LLC was a company managed by USPLabs, LLC. However, in an attempt to disguise the true ownership interests and conceal the responsible entities, after a Request for Judicial Notice was filed in this case to establish alter ego, an "amendment" was filed which removed USPLABS, LLC as "manager" and listed the entity USPLABS JACK3D, LLC as its own manager, and the address was changed from Texas to an obscure Wyoming address. Despite the clever maneuvering, it is clear Geissler and Doyle acting through USPLabs LLC still own and control both the Jack3d trademark and the USPLABS JACK3D, LLC company.

10. It is also clear Geissler and Doyle, acting through USPLabs, LLC, also dominate and control many other USP entities and their respective trademarks:

- Additionally, there are thirteen other "USPLABS" companies registered in Wyoming (not including USPLABS JACK3D, LLC). At least nine of those 13 other USP companies were, at one time, listed by the Wyoming Secretary of State as "managed" by USPlabs LLC.

- Again in an attempt to disguise the true ownership interests, and in response to the alter ego motion raised in this case, similar "common amendment(s)" were filed on the same day as that filed for USPLABS JACK3D, LLC for nearly every company surreptitiously removing USPLABS, LLC as "manager" of the respective entity.

- This ownership interest is furthered by the fact that the 14 USP companies correspond to a product sold by USPLABS LLC.

- In addition to USPLABS JACK3D, LLC, USPLABS LLC owns or at one time owned the trademark corresponding to a subsidiary they established in 12 other instances.

11. Based on publicly filed trademark documents and corporate registrations and the timing of strategic changes, it is evident USPLABS, LLC, and in turn Geissler and Doyle, completely dominate the USP enterprise and they are in fact alter egos.

II. Use of the Same Offices or Employees

12. USPLABS LLC and USPLABS JACK3D, LLC, listed the same physical address: "10761 King William Dr., Dallas, TX 75220" until May 2013 when the JACK3D, LLC addresses were changed on Wyoming state records to a small storefront office bordering a residential neighborhood in Cheyenne, WY.

13. Similarly, nine of the 13 other USP companies listed their principal or mailing address as "10761 King William Drive, Dallas, TX 75220", one listed the address of the filing attorney, two more listed the former address of USPLabs LLC in Dallas, TX, and the last listed both the attorney and King William Drive as a principal address.

14. Subsequently, the addresses of all these entities were changed to the same Cheyenne, WY address. Notably, all these amendments took place after the Plaintiffs briefed the issue of alter ego and personal jurisdiction. The intent of USP to thwart an attempt to establish alter ego and hide the true nature of these subsidiaries is evident from the sequence of events. Despite the maneuver, USP made a fatal flaw since despite changing the address of USPLABS JACK3D, LLC in the corporate registration to the Cheyenne address, they forgot to change the address listed on the

trademark for "USPLabs Jack3d" which still reads "10761 King William Drive" (the same as USPLABS, LLC.) This oversight is best explained by the true fact that USPLABS JACK3D, LLC is operated out of the same address as USPLABS, LLC. The intent to disguise the fact that the USP entities all share the same address and are shells operating through the parent USPLABS, LLC is clear. It is this kind of transparent maneuvering that is at the center of alter ego theory.

15. So too do at least USPLabs, LLC, and USPLabs JACK3D, LLC share common executive officers: Chief Financial Officer Lonnie Clark. Doyle and Geissler are the President and CEO of USPLabs, LLC, respectively.

III. Use of Same Attorney

16. Additionally, USPLABS LLC, USPLABS JACK3D, and USPLABS HOLDINGS use the same attorney to file and monitor their registered trademarks. Not without coincidence all three are represented in the instant matter by the same firm.

17. This same attorney filed or is the attorney of record for trademarks for all of the other USP products corresponding to the other USP entities.

IV. Lack of Corporate Formalities

18. USPLABS JACK3D and the other subsidiaries do not observe corporate formalities. They do not hold shareholder meetings, they do not possess bylaws, they otherwise fail to observe corporate formalities.

19. Thus, USPLABS LLC is the parent of, and through Geissler and Doyle, dominates multiple subsidiaries each of which apparently have no operational function, with the design being a common enterprise of marketing, selling and distributing dietary supplements.

V. Injustice/Use of Corporate Form to Defeat a Rightful Claim

20. Failure to disregard the separate corporate existence of the USP Defendants will result in injustice since Geissler and Doyle founded, control and dominate the parent and multiple subsidiaries and use the corporate form to shield themselves from liability for their wrongdoing. USPLABS, LLC constructed a corporate shell game in an effort to market a dangerous and illegal

product which was the subject of FDA enforcement and was ultimately the subject of a large-scale destruction of products.

21. The USP enterprise is designed such that multiple subsidiaries are named after individual USP products even though trademarks for most of those products are owned directly by USPLABS LLC. They were all founded by (directly or indirectly) USPLABS LLC. Geissler and Doyle have set up instrumentalities for each of their products even though they directly own the rights to most of those products in an apparent attempt to further their enterprise of selling illegal dietary supplements.

22. Moreover, the only current function of USPLABS JACK3D is to hold the trademark to Jack3d. USP JACK3D must license to USPLABS, LLC use of this mark. The only purpose of USPLABS JACK3D, LLC is to further the illegitimate purpose of shielding assets of USPLABS LLC which transfers money and profits to the subsidiaries in anticipation of litigation, to make USPLABS LLC judgment proof and to defeat a rightful claim. This wrongdoing is further supported by the timing of the common amendments removing USPLABS LLC as a manager and changing the corporate addresses after Plaintiffs briefed the instant alter ego issues in an attempt to defeat what is otherwise a clear case of alter ego and further protect and insulate USPLABS, LLC from judgment and to defeat the rightful claims of Plaintiffs. With no operational purpose, allowing the separate corporate existence of the USP Defendants would thus work an injustice and permit an abuse of the corporate privilege.

23. Additionally the corporate fiction of USP DEFENDANTS, and each of them, were a sham to perpetrate a fraud as herein alleged and to shield GEISSLER, DOYLE and the responsible USP entities from liability for breach of their legal and equitable duties. Adherence to the fiction of the separate existence of the USP DEFENDANTS would promote injustice and result in inequity to Plaintiffs.

24. At all relevant times, the USP DEFENDANTS were each engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling, directly and indirectly, through third parties or related entities Jack3d and/or the Defendants are otherwise responsible as corporate successors for the liabilities of the entities that

designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold Jack3d.

25. Upon information and belief, at all relevant times, the USP DEFENDANTS were present and doing business in the State of Texas.

26. At all relevant times, the USP DEFENDANTS transacted, solicited, and conducted business whether through retail stores or through internet merchants in the State of Texas and derived substantial revenue from such business.

27. At all relevant times, the USP DEFENDANTS expected or should have expected that their acts would have consequences within the United States of America and within the State of Texas.

II. Retailers

28. Defendant GNC CORPORATION ("GNC") is a Delaware corporation with its principal place of business located in Pittsburgh, Pennsylvania. Defendant GNC conducted regular and sustained business in the State of Texas and throughout the nation, including the sale of Jack3d by its retail outlets, affiliates and franchisees. Defendant GNC was regularly engaged in the business of packaging, distributing, and/or selling, either directly or indirectly, through third parties or related entities, non-prescription nutritional/dietary supplements for sale to, and use by, members of the general public, and as a part of their business said Defendant sold the Jack3d purchased by, ingested by and causing harm to Plaintiff-Decedent as alleged herein.

29. At all times herein alleged, each of the acts of the employees of GNC were on behalf of, for the benefit of, at the direction of, and at the behest of GNC and were ratified by GNC. Further, each of the acts of the GNC employees were done pursuant to and in accordance with corporate policy.

30. The true names or capacities, whether individual, corporate, or otherwise, of Defendants DOES 1 through 500, inclusive, are unknown to Plaintiffs who are therefore ignorant of the true names and sues said Defendants by such fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein by fictitious names is in some manner legally responsible

for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiffs as alleged herein.

31. At all times hereinafter alleged, "DEFENDANTS" include all herein named Defendants as well as Defendants DOES 1 through 500, inclusive.

32. At all times herein alleged, each of the DEFENDANTS was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of each of the remaining DEFENDANTS herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other DEFENDANTS, knowing that their conduct constituted a breach of duty owed to Plaintiffs.

PLAINTIFF-DECEDENT

33. At all relevant times, Plaintiffs LEANNE SPARLING and MICHAEL J SPARLING were residents of the State of California.

34. Plaintiffs LEANNE SPARLING and MICHAEL J SPARLING are the parents of, and sole successors in interest to the Plaintiff-Decedent MICHAEL L SPARLING.

35. Plaintiff-Decedent MICHAEL L SPARLING was a domicile of California since although at the time of his injury he was temporarily residing in the State of Texas, he intended to return to California. He had no intent to remain in Texas indefinitely. He was there temporarily. He was registered to vote in California, paid taxes in California, his family was located in California, and he was only physically present in Texas for a little over one month as opposed to California where he resided his entire life.

36. In or about late April until his death on June 1, 2011, Plaintiff-Decedent ingested Jack3d purchased from a GNC store in Sacramento, California and at Fort Bliss, El Paso, Texas.

37. At no time did Plaintiff-Decedent take more than the recommended dosing regimen contained in Jack3d.

38. On the morning of June 1, 2011, the Plaintiff-Decedent MICHAEL L SPARLING took the recommended dosage of Jack3d, which he purchased from a GNC on the Fort Bliss base.

Shortly thereafter he engaged in physical training with his unit during which he collapsed, requiring immediate medical attention.

39. On June 1, 2011, after taking the recommended dosing of and as a result of Jack3d manufactured by USP and NAI and sold by GNC, Plaintiff-Decedent suffered cardiac arrest, hyperthermia, rhabdomyolysis, disseminated intravascular coagulation, death and related injuries.

FACTUAL BACKGROUND

The JACK3D

40. Jack3d is a trademarked product sold by USP. Jack3d contains the following ingredients as depicted in its label:

41. One of the ingredients of Jack3d is DMAA. DMAA is a dangerous sympathomimetic. Jack3d additionally contains caffeine, thereby increasing the sympathomimetic qualities and dangers of DMAA.

42. Jack3d additionally contains CarnoSyn a propriety beta-alanine product made by NAI, which is also dangerous.

43. Additionally, Jack3d does not work.

44. Jack3d is sold through retailers such as GNC in California, Texas, and across the country.

DMAA, a Dangerous Chemical Shunned by the Pharmaceutical Industry, Reemerges in Dietary Supplements

45. DMAA is an active ingredient contained in Jack3d manufactured, marketed, distributed, and sold by DEFENDANTS.

46. DMAA, also known as methylhexanamine (MHA), is an aliphatic amine compound that has properties mimicking those of the endogenous neurotransmitters of the sympathetic nervous system. As such, it belongs to a group of compounds known as "sympathomimetics." Members of this class include ephedrine and the amphetamines.

47. While sympathomimetics are used by physicians to increase blood pressure and to constrict blood vessels, they are also widely abused because of their perceived ability to enhance athletic performance and in some cases induce euphoria.

48. Sympathomimetic compounds were originally developed in the 19th century as drugs for the treatment of cold symptoms. Compounds capable of constricting blood vessels were actively sought. First cocaine, then epinephrine, and in 1925 ephedrine, were used for this purpose. However, the adverse effects, inability to provide long term relief and addictiveness eventually resulted in the search for a similarly structured chemicals Through trial and error, it was eventually determined that slight modification of the ephedrine molecule would result in molecules having equivalent vasoconstrictor properties to ephedrine. These modifications eventually led to the development of DMAA, originally named Fouramine.

49. In 1943, DMAA was introduced as a nasal decongestant by Eli Lilly under the trade name of Forthane. For unexplained reasons Lilly voluntarily withdrew Forthane from the market in 1983. No other prescription or over-the-counter drugs or dietary supplements used DMAA from 1983 until approximately 2005. In 2005, Patrick Arnold, a chemist convicted for his role in the BALCO baseball steroid scandal, reintroduced MHA/DMAA as an over-the-counter dietary supplement with amphetamine-like qualities. It was marketed as an alternative to ephedrine. The use of DMAA in dietary supplements spread and eventually found its way into Jack3d.

50. Animal testing in a variety of models demonstrated that DMAA was a potent pressor drug causing increases in blood pressure that is comparable to ephedrine. The structure of and mechanism by which DMAA increases blood pressure is thus similar to ephedrine. Dietary supplements containing ephedra, the natural form of ephedrine, were ordered off the market by the FDA in 2004, because the blood pressure and heart rate effects were associated with a number of serious adverse events to users including heart attack, stroke and death.

Defendants' Jack3d Claims

51. DEFENDANTS conveyed their deceptive claims about the Jack3d through a variety of media, including television, newspapers, magazines, direct mail, the Internet, point of sale displays, and on the Jack3d labels and packaging. In addition, retailers, including Defendant GNC, promoted, marketed and sold Jack3d in stores, on its websites and through other mediums of advertising.

52. In their advertisements and on their website, USP represented that Jack3d is:

- "Voted # 1 Pre-Workout"
- "Backed by 2 Peer-Reviewed Published Clinical University Research Studies"
- "Jack3d is now backed by multiple University studies**, including double-blind, placebo-controlled research.**"
- "Jack3d – **proven in the real world & in the lab** . . ."

These representations were false, misleading and deceptive.

53. USP further represented on its website that

- "The hemodynamic response to acute ingestion was assessed as well. OxyElite Pro (another DMAA-containing product made by USP) did not result in a statistically significant change in heart rate or diastolic pressure, but did cause a statistically significant change in systolic blood pressure from baseline. This increase was mild and transient, and was similar to the changes reported in the scientific literature for subjects ingesting an amount of caffeine equivalent to 2-3 cups of coffee."

- "Jack3d, which contains DMAA, was well tolerated and no serious adverse events were noted."

- "At the beginning and end of the study, blood pressure, heart rate and various indicators of renal and liver function were assessed. The study found that there were no statistically significant changes from baseline to the end of the study. No serious adverse events were noted."

- "NEWLY RELEASED, GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS' DMAA SUPPLEMENTS ARE SAFE AND EFFECTIVE."

USP's representations were false, misleading and deceptive.

54. USP also advertises on fitness blogs and websites such as bodybuilding.com making similar representations. In fact, Defendant GEISSLER even writes letters on such sites claiming Jack3d:

- will make "everyone dominate the weights and have crazy, lasting energy along with sick, muscle-engorging pumps,"
- contains a "synergistic combination (which) is KEY,"
- is not like other products, which are "a bunch of ingredients thrown together haphazardly," and

- uses "only the highest quality ingredients."

However, these like the other misrepresentations with respect to the safety, efficacy, and purity of Jack3d, are false, misleading and deceptive.

55. USP has also issued press releases, which promote the purported safety and efficacy of Jack3d. For example, on February 24, 2012, just weeks after the Defense Department pulled Jack3d from military store shelves, USPLabs issued a press release entitled "USPLabs Jack3d Peer-Review Clinical Safety Study Published." In its press release, USPLabs stated:

> USPlabs Jack3d™ and OxyElite Pro® are among the most studied finished dietary supplements ever sold. This most recent study is the 7th peer-reviewed, published clinical trial supporting the safe use of DMAA when used as directed, in addition to an industry estimated over one billion servings consumed by satisfied customers. More specifically, Jack3d™ & OxyElite Pro® have 5 clinical trials that show they are safe when used as directed.

56. USP made similar statements about the purported safety and efficacy of the Jack3d in another press release, dated March 7, 2012, entitled "USPlabs Shares Results of Seven Peer-Reviewed DMAA Safety Studies as Part of Scientific Review on Jack3d™ . . . ."

57. USP owns and operates another website, www.dmaaresearch.com, where it makes similar statements about the purported research supporting the safety and efficacy of DMAA. For example, on its dmaaresearch.com website USP lists "[a]ll current available clinical data on DMAA," which are also purportedly "conducted by independent experts and published in respected journals." As discussed herein, the "seven" studies cited by USP and discussed on its websites, are not conducted by independent experts, are not published in legitimate journals, and furthermore, demonstrate that Defendants' claims about the safety and efficacy of Jack3d are unsubstantiated, false and deceptive.

58. USP's websites, including www.USPLabsDirect.com and www.DMAAResearch.com are available to the general public and USP's advertisements in other media promote these websites.

59. GNC further enabled USP to make representations concerning the quality of the Jack3d. The retailers that sold the Jack3d adopted, and are responsible for, the representations USP made on packaging regarding the safety and efficacy of the Jack3d, when they decided to place such Jack3d on their store shelves, on military bases and on retail websites, and thereafter advertised and sold such Jack3d to Plaintiff-Decedent. Further, GNC advertised and included a prominent link on its own website to USP's Jack3d websites.

60. GNC further reinforces these claims of safety and efficacy. For example, it states that Jack3d is "University Studied." The representation that Jack3d is "universally studied" implies that the studies universally demonstrate safety, when instead they demonstrated blood pressure and heart rate findings which do not demonstrate safety.

61. Despite the overwhelming evidence that Jack3d is neither safe nor effective, GNC continued to make public statements to the contrary, assuring consumers that DMAA is safe. For example, in response to the FDA's 2012 warning letter GNC stated: "We are completely opposed to this unilateral, factually and legally unfounded action by the FDA and we believe the large consumer base that has safely used products containing DMAA in millions of doses will also oppose it." GNC further stated that "DMAA is perfectly safe when taken as directed."

62. In February 2012, under pressure from the Department of Defense after the death of two soldiers from Jack3d, including Plaintiff-Decedent, GNC agreed to pull its DMAA-containing products, including Jack3d, from its stores on military bases. Nevertheless, GNC continues to market and sell Jack3d to consumers in its other retail stores and through its online website.

63. Without requisite proof, DEFENDANTS also claim that Jack3d is safe, effective, and proven by research. For the types of marketing claims at issue, the Federal Trade Commission rules, mirroring common law duties of fair representation, require that DEFENDANTS actually have the level of proof claimed, here clinical proof, at the time the claims are made. However, DEFENDANTS did not, and have never possessed the requisite proof.

64. The health problems associated with Jack3d manifest themselves when consumers, including Plaintiff-Decedent as alleged herein, use the product at recommended dosage levels. In

fact, in a warning letter sent to USP, FDA expressed its opinion that Jack3d is adulterated under §402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §342, in that Jack3d presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling:

> . . . Oxy Elite Pro and Jack3d are adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that dimethylamylamine will reasonably be expected to be safe as a dietary ingredient. In fact, dimethylamylamine narrows the blood vessels and arteries, which increases cardiovascular resistance and frequently leads to elevated blood pressure. This rise in blood pressure may increase the work of the heart such that it could precipitate a cardiovascular event, which could range from shortness of breath to tightening of the chest and/or a possible myocardial infarction (heart attack).

65. Notwithstanding significant and mounting evidence that Jack3d is falsely labeled, ineffective, and poses significant health risks, DEFENDANTS did not recall Jack3d, which remains on the market. Despite the evidence of significant health risks, DEFENDANTS continued to make material misrepresentations and omissions on Jack3d packaging and labeling. Moreover, as stated herein, DEFENDANTS continue to downplay the true health risks involved with consuming Jack3d.

66. Remarkably, USP has even filed suit in the Northern District of Texas (Case 3:12-cv-01605-O) against an individual and entity for allegedly false and disparaging statements about Jack3d. The statements included well-known, incontrovertible facts about Jack3d (which contains DMAA) such as that it is an "amphetamine-like compound," and that it "speeds up your heart rate." USP continues to not only make misrepresentations to the public about the nature of DMAA and

Jack3d as alleged above, it so vehemently denies their sympathomimetic qualities that it is suing individuals for defamation. Making such action even more reprehensible is that USP's own funded studies concede DMAA is a "simple aliphatic amine with sympathomimetic properties" (Whitehead, PN, Schilling, BK, Farney, TM, Bloomer, RJ. Impact of a dietary supplement containing 1,3-dimethylamulamine on blood pressure and bloodborne markers of health: a 10-week intervention study. *Nutrition and Metabolic Insights* 2012:5 33-39.) as does the FDA warning letter sent to USP. This lawsuit was brought in an attempt to intimidate and stifle the dissemination of essential safety information about Jack3d.

Studies Promoted by USP Demonstrate Lack of Safety or Efficacy for Jack3d

I. Claims Regarding Safety

67. Defendants also claim that the safety and efficacy of Jack3d has been shown in clinical studies. For example, at its usplabsdirect.com and dmaaresearch.com websites, USP lists seven studies involving DMAA and states: "NEWLY RELEASED, GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS' DMAA SUPPLEMENTS ARE SAFE AND EFFECTIVE". However, none of these studies constitutes reliable scientific or clinical proof.

68. Despite claims made by USP in its marketing and advertising, as detailed above, Jack3d is not scientifically tested or proven to provide, and does not provide the advertised health benefits of "increase[d] . . . fat breakdown and energy expenditure," "reduced fat mass," "weight loss" and other similar benefits. Accordingly, USP's marketing claims that Jack3d is proven, including because it is "UNIVERSITY STUDIED," "Scientifically Reviewed," and "PHARMACIST FORMULATED" are false, misleading, and likely to deceive the ordinary consumer.

69. Properly-conducted human studies do not demonstrate the safety or efficacy of the Jack3d or DMAA. In fact, human data regarding the safety or efficacy of DMAA are few and are the majority are funded by the USP Defendants.

70. Even Defendants' own purported clinical proof demonstrates the falsity of its claims. On its websites, usplabsdirect.com (which is referred to on the Jack3d's labeling) and dmaaresearch.com, USP lists "seven" studies on DMAA containing products. USP characterizes one study that had male and female cohorts as two studies in order to state "seven" DMAA studies substantiate its claims. USP admits its involvement and funding of five of the seven studies. Furthermore, none of these studies provide substantiation for the marketing claims

a. McCarthy, Farney et al. 2012: Twelve subjects ingested OxyELITE Pro or a placebo over two days. USPLabs provided funding for the study, which analyzed subjects' blood markers and metabolic rates. The authors acknowledged that "little objective scientific evidence is available" on DMAA, and that "some subjects reported feeling 'jittery', 'on-edge', 'sweaty', and 'shaky', sometimes involving cold sweats, a racing heart beat, and poor sleep quality on the night of treatment." According to the authors, and with respect to DMAA, "no published reports are available pertaining to these [weight/fat loss] effects in human subjects." (emphasis added). The authors also noted that subjects consuming DMAA-containing OxyELITE Pro experienced increased heart rate and blood pressure. The study concluded that "well-controlled intervention trials are needed in order to determine the chronic effects of the supplement on body weight/fat loss and associated metabolic and biomechanical markers of health."

b. McCarthy, Canale et al. 2012: Thirty-two subjects ingested OxyELITE Pro or a placebo over eight weeks. The study was funded by USPLabs. Five of sixteen subjects who consumed OxyELITE Pro reported jitters and sleeplessness when consuming two capsules per day. The authors observed an increase in resting heart rate for those consuming DMAA-containing OxyELITE Pro and noted that the lack of control of subjects' dietary intake was a limitation.

c. Farney, McCarthy et al. 2012: Once per day for two weeks seven men ingested Jack3d, and six subjects ingested OxyELITE Pro. The study was funded by USPLabs. The authors noted that the lack of a placebo is a limitation of this study. Because appetite was lower on subjects consuming OxyELITE Pro, but not Jack3d, the authors observed that it was possible that ingredients other than DMAA or caffeine may be responsible for appetite suppression. According to the study, "Based on our data, which admittedly involved a very small number of subjects, it appears that such products should be avoided by individuals who are hypersensitive [] or who are pre-hypersensitive." Subjects reported sleeplessness, anxiousness, feeling of chills, tingling, sweating, and shakiness.

d. Bloomer, Schilling et al. 2012: Twenty-five men were assigned to consume a placebo or Jack3d. The study was funded by USPLabs. Systolic blood pressure increased in those consuming Jack3d. The authors stated that "Due to the fact that our sample size is small, additional well-designed experiments of similar scope, inclusive of larger sample sizes, are needed to extend the findings presented within." The authors also noted that only "some support" for safety was provided, and that "more work is needed involving a larger intervention period and the inclusion of additional measures of health [], to more fully elucidate the safety or oral [DMAA]."

e. Bloomer, Harvey et al. 2011: Ten men consumed five different amounts of DMAA. No placebo was used, which the authors conceded was a limitation to this study. The authors noted that no study had tested DMAA's effect on heart rate and blood pressure in humans. The study found that consuming DMAA with caffeine results in increased systolic blood pressure, diastolic blood pressure, and rate pressure product. Dr. Bloomer disclosed his conflicts of interest with USPlabs and other nutritional supplement companies.

f. Bloomer, McCarthy et al. 2011: Twelve subjects ingested placebo, caffeine, DMAA, or DMAA plus caffeine over four days and immediately prior to competing a 10k run. The authors noted that "[t]he literature pertaining to the use of [DMAA] is scant." The authors concluded that DMAA increases systolic blood pressure, and had no impact on the outcome of greatest interest – run time.

71. USP made further misrepresentations on its website that two studies conducted by Dr. Richard Bloomer were conducted by an "independent scientist without the involvement of the company," these studies like the other five are all from the same laboratory at the University of Memphis. Dr. Bloomer was a lead researcher in each of the seven studies cited by USP. Moreover, Bloomer, Harvey et al. 2011, which USP claims was conducted by an independent scientist, concedes that the opposite is true by stating at the conclusion of the study "CONFLICT OF INTEREST STATEMENT – Richard J. Bloomer, PhD discloses conflicts of interest with . . . USPLabs." On information and belief, Dr. Bloomer has received $524,332 in funding from USPLabs: $132,860 (2010-2011), $225,600 (2011-2012), $128,860 (2012-2013), and $37,012 (2012-2013).

72. Bloomer, Harvey et al. 2011 further reported that both caffeine and DMAA increased diastolic and systolic blood pressure separately (with the effect of DMAA being greater than caffeine), and that when the two ingredients were combined the healthy study volunteers experienced mean blood pressures of 140 mm Hg, a 20% increase consistent with hypertension despite low normal pre-exposure pressures. The data from Bloomer, Harvey et al. 2011 thus demonstrates that DMAA given in the proprietary formulation as compared to alone has a less pharmacologically clean effect and results in a greater increase in rate-pressure product ("RPP," a measure of myocardial work or cardiovascular risk).

73. USP further mischaracterizes the sympathomimetic effects of DMAA, specifically including the statistically significant increased blood pressure found by one study caused by Jack3d, by comparing the risk to mild amounts of coffee, a universally regarded safe sympathomimetic when used in isolation:

> The hemodynamic response to acute ingestion was assessed as well. OxyElite Pro did not result in a statistically significant change in heart rate or diastolic pressure, but did cause a statistically significant change in systolic blood pressure from baseline. This increase was mild and transient, and was similar to the changes reported in the scientific literature for subjects ingesting an amount of caffeine equivalent to 2-3 cups of coffee. (emphasis added)

This statement with respect to acute ingestion is misleading given the study results demonstrate that "Compared to pre-ingestion and in general, both supplements resulted in an increase in SBP, DBP, and RPP from 5%-15%, with a peak occurring at the 60 or 90 minute post-ingestion time." The study went on to highlight the acute cardiovascular risks:

> As expected based on the pharmacologic profiles of caffeine and of 1,3-dimethylamylamine, acute intake of dietary supplements containing these agents results in an increase in myocardial work. Specifically, SBP is increased significantly in response to treatment, while DBP, and RPP increase to a lesser extent.

74. The "seven" cited studies do not constitute substantiation for Defendants' claims relating to safety and efficacy, and in fact, are proof that Jack3d is unsafe and ineffective. First, there are no independent studies performed by researchers without conflicts: each of the studies come from a single laboratory funded by USP, and are led by a researcher who has received over $500,000 from USP. Second, the studies, which contain a total of 99 subjects, are grossly underpowered (a fact repeatedly conceded in the reports themselves), restricted to a very young population, and there is no attempt to characterize the pharmacokinetics or purity of the drugs. Despite the lack of reliability or validity of the purportedly independent studies, the studies present a relatively consistent picture. DMAA, particularly when combined with caffeine or other agents, causes highly significant increases in blood pressure in healthy, resting individuals within one hour of consumption in a manner consistent with its known action as a vasoconstrictor. These sorts of changes should be anticipated to cause substantial and possibly dangerous increases in blood pressure during exercise (particularly weight lifting, cycling, or other resistance exercise). Vasoconstriction during exercise would increase myocardial oxygen consumption leading to an

increased risk for cardiovascular events like heart attack and stroke. In other words, the studies themselves, flawed as they are, demonstrate the dangerous and synergistic sympathomimetic effects of the DMAA formulation contained in Jack3d. In fact, Defendants do not deny the synergistic effects of DMAA and caffeine stating on their website "a common synergistic combination."

75. Thus, USP knew, or in the exercise of reasonable care ought to have known, from their own studies that DMAA, when used in isolation or in conjunction with the other ingredients contained in Jack3d including caffeine and CarnoSyn, is dangerous and could injure or kill consumers like Plaintiff-Decedent. In fact, USP knew or should have known long before its own studies that DMAA could cause cardiovascular adverse effects based on the fact DMAA is in the same class of chemicals as amphetamines.

76. In making these and similar representations in advertising and in the Jack3d product labeling, USP misled users and Plaintiff-Decedent about the risks of Jack3d. USP also failed to adequately warn users of the potential serious dangers of DMAA toxicity in susceptible users which USP knew or should have known might result from consuming Jack3d. USP widely and successfully marketed the products throughout the United States by, among other things, conducting a marketing campaign which misrepresented the testing for efficacy and potential risks of the products in order to induce widespread consumption.

77. Likewise, GNC knew or should have known that DMAA could cause cardiovascular adverse effects based on the fact DMAA is in the same class of chemicals as amphetamines.

78. GNC joined in the misrepresentations about DMAA, by asserting in its marketing of Jack3d that GNC conducts a review and has a requirement that the products it sells have labels that truthfully disclose health and safety issues and that the ingredients be safe. GNC represents that it exercises the highest standard of care in the nutritional supplement industry by "demanding truth in labeling, ingredient safety." Moreover, on information and belief, GNC considered, reviewed and rejected the idea of selling its own propriety products containing DMAA with knowledge that DMAA could injure consumers.

II. Claims Regarding Efficacy and Composition

79. USP similarly knew, or in the exercise of reasonable care ought to have known, that Jack3d is not effective for weight loss or any other health benefits claimed by USP.

80. USP additionally knew that consumers believe that natural supplements are more healthful and less dangerous than synthetic, chemically produced supplements. USP represented in its advertising and marketing that Jack3d is a natural dietary supplement, when in fact it knew that the active ingredient DMAA, was not a natural ingredient but was a chemically compounded, synthetic ingredient. In fact, in a response letter to FDA on May 15, 2012, it acknowledged DMAA was synthetically created. USP further knew that DMAA is not contained in natural substances like geranium oil. It made these false representations that Jack3d is a natural product to mislead and falsely reassure consumers that Jack3d is a safe product.

81. FDA denied that DMAA is a natural as opposed to synthetically-created compound: "The agency additionally warned the companies that synthetically-produced DMAA is not a 'dietary ingredient' and, therefore, is not eligible to be used as an active ingredient in a dietary supplement. DSHEA defines a dietary ingredient as a vitamin, mineral, amino acid, herb or other botanical, a dietary substance for use by man to supplement the diet, or a concentrate, metabolite, constituent, extract, or combination of these substances."

82. The purpose of these submission requirements for dietary supplements is to protect consumers from exposure to new, synthetically created dietary supplements which are not demonstrated to be safe and effective, the exact situation here.

83. USP attempted to assuage concerns from critics, FDA and concerned consumers about the safety of DMAA by suggesting DMAA comes from a naturally occurring herb and is therefore safe. However, DMAA is a dangerous synthetically-created chemical known by industry insiders like USP to display sympathomimetic side effects. A single Chinese study claims that DMAA occurs naturally in geranium oil (Ping Z, Jun Q, and Qing L. A study on the chemical constituents of geranium oil. Journal of Guizhou Institute of Technology 25: 1996.) The New Zealand National Measurement Institute performed a rigorous evaluation of this claim and found it impossible to substantiate (Lisi A, Hasick N, Kazlauskas R, and Goebel C. Studies of methylhexaneamine in supplements and geranium oil. Drug Test Anal 2011.) Health Canada

likewise could find no evidence that DMAA occurs in nature (Health Canada, Health Products and Food Branch. Classification of 1,3-dimethylamylamine (DMAA). http://www.scribd.com/doc/82744576/DMAA-Health-Canada-2011. Accessed March 22, 2012.)

84. Additionally, in a study published June 25, 2012 (ElSohly, MA, et al., Pelargonium oil and Methyl Hexaneamine (MHA): Analytical approaches supporting the absence of MHA in authenticated Pelargonium graveolens plant material and oil. Journal of Analytic Toxicology: published online: June 25, 2012), the authors concluded, after numerous and varied tests of geranium oils and plants, that geranium oils and plants contain no detectable levels of DMAA. This research refutes any claims that synthetic DMAA is identical to naturally derived ingredients. It is impossible for synthetic DMAA to be identical to the natural geranium plant and oil since geranium plant and oil do not contain detectable levels of DMAA.

85. Despite these facts, USPlabs has circulated a letter purporting to have proof from two laboratories claiming that DMAA can be found in geranium oil. The data are allegedly not available for review because they have been submitted for publication. USP persists in its representations that DMAA is a natural chemical to reassure consumers that the product is safe and natural, when in fact it is neither.

Adverse Events From DMAA Pile Up and FDA Warns USP

86. On December 6th, 2011, the US Army removed all DMAA containing compounds from its commissaries. This action followed the deaths of two soldiers believed to be due to Jack3d, including that of Plaintiff-Decedent. A case series from New Zealand reported three cases of cerebral hemorrhage in adults taking DMAA (Gee P, Tallon C, Long N, Moore G, Boet R, Jackson S. Use of Recreational Drug 1,3-Dimethylethylamine (DMAA) Associated With Cerebral Hemorrhage.) In one case, a 41 year old man developed a systolic blood pressure of 240 mm Hg thirty minutes after taking a DMAA supplement and bled into his brain. Another published report attributes stress-induced cardiomyopathy to use of DMAA (Salinger L, Daniels B, Sangalli B, Bayer M. Recreational use of bodybuilding supplement resulting in severe cardiotoxicity. Clin Toxicol. 2011;49(6):573-574.) Pieter Cohen, a Harvard internist, has recently drawn attention to DMAA in a

letter to the Archives of Internal Medicine (Cohen PA. DMAA as a Dietary Supplement Ingredient. Arch Intern Med. 2012 May 7 [Epub ahead of print].)

87. In a letter addressed to USPLabs from FDA dated April 27, 2012, the Agency warned that it had received 42 adverse event reports on products containing DMAA, including cardiac disorders, nervous system disorders, and death. Many of those adverse event reports were specifically for Jack3d and stretch back to early 2010, if not earlier.

88. Daniel Fabricant, director of FDA's Dietary Supplement Program (DSP) stated "Before marketing products containing DMAA, manufacturers and distributors have a responsibility under the law to provide evidence of the safety of their products. They haven't done that and that makes the products adulterated." FDA challenged manufacturers to demonstrate that DMAA was in use as a dietary supplement prior to 1994.

89. USP attempted to deflect attention away from safety concerns and to misrepresent the actual risks of DMAA by stating numerous times on its website that "no serious adverse events were noted in the study." USP neglected to inform consumers and the public, including Plaintiff-Decedent herein who relied on USP's representations and misleading comments, that in fact FDA had received dozens of serious adverse events from people taking DMAA, including death.

COUNT I

NEGLIGENCE

(Against All Defendants)

90. Plaintiffs incorporate by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

91. At all times herein mentioned, DEFENDANTS, and each of them, had a duty to exercise reasonable care in the research, development, testing for safety, formulation, manufacture, hiring of and use of qualified scientific or medical personnel, labeling, packaging, promotion, advertising, marketing, distribution, sale, and otherwise releasing into the stream of commerce Jack3d.

92. DEFENDANTS, and each of them, breached their duty of reasonable care to Plaintiffs in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and/or sold Jack3d. Specifically, DEFENDANTS failed to exercise reasonable care in ways which included, but were not limited to, one or more of the following particulars:

a. In their failure to warn or instruct and/or adequately warn or adequately instruct the public and consumers, including Plaintiff-Decedent herein, of the dangerous and defective characteristics of Jack3d;

b. In their failure to warn or instruct and/or adequately warn or adequately instruct the public and consumers, including Plaintiff-Decedent herein, of the propensity of Jack3d to cause side effects, serious injury and death;

c. In their failure to adequately represent the result of clinical trials before marketing Jack3d;

d. In representing that Jack3d was safe and effective for its intended use when, in fact, the product was unsafe for its intended use;

e. In failing to perform appropriate, reliable and valid pre-market testing of Jack3d;

f. In failing to perform appropriate post-market testing of Jack3d;

g. in failing to disclose to consumers and Plaintiff-Decedent adverse events received from FDA by users of DMAA; and

h. In failing to perform appropriate post-market surveillance of Jack3d.

93. DEFENDANTS, and each of them, knew or should have known that consumers, such as Plaintiffs herein, would foreseeably suffer injury as a result of the DEFENDANTS' failure to exercise reasonable and ordinary care.

94. As a direct and proximate result of DEFENDANTS' carelessness and negligence, and of the unreasonably dangerous and defective characteristics of Jack3d, Plaintiffs suffered severe and permanent injuries. Plaintiff-Decedent endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff-Decedent incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and were otherwise physically, emotionally, and economically injured. Plaintiff-Decedent suffered severe pecuniary loss. Plaintiffs also suffered

unique injuries as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

COUNT II

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against All DEFENDANTS)

95. Plaintiffs incorporate by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

96. At all times material to this action, the DEFENDANTS, and each of them, were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling, directly and indirectly, through third parties or related entities the dietary supplement Jack3d, which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiff-Decedent.

97. At all times material to this action, Jack3d was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the respective DEFENDANTS in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Plaintiff-Decedent, to risks which exceeded the benefits of the drug;

b. The drug did not perform as safely as an ordinary consumer would have expected it to perform when used in an intended or reasonably foreseeable way;

b. The drug was insufficiently tested;

c. The drug caused harmful side effects that outweighed any potential utility;

d. The drug was more dangerous than other dietary supplements on the market; and

e. The drug was not accompanied by adequate labeling or instructions for use to fully apprise the public and consumers, including Plaintiff-Decedent, of the potential risks and serious side effects associated with its use.

98. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential risk of harm would have concluded Jack3d should not have been marketed in that condition.

99. There existed safer alternative designs, but DEFENDANTS, and each of them, chose to market a more dangerous design.

100. At all times relevant herein, DEFENDANTS, and each of them knew that Jack3d would be purchased by members of the general public and would be used by such purchasers without a prescription and without any inspections for defects, and would rely upon the representations made by each of the DEFENDANTS on the product label and in other promotional and sales materials.

101. At all times material to this action, Jack3d was expected to reach, and did reach, consumers in the State of California and throughout the United States, including Plaintiff-Decedent, without substantial change in the condition in which it was sold.

102. DEFENDANTS, and each of them, knew or should have known of the defective nature of Jack3d but continued to research, develop, design, test, manufacture, package, formulate, inspect, label, distribute, market, promote, sell and otherwise release these products into the stream of commerce so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by their products, including serious cardiovascular disorders, stroke, heart attack, dizziness, loss of consciousness, death, and other health problems.

103. At all times, Plaintiff-Decedent used Jack3d for its intended or reasonably foreseeable purpose.

104. As a direct and proximate result of the defective and unreasonably dangerous condition of Jack3d and of its failure to perform safely, Plaintiffs suffered injuries as set forth above.

COUNT III

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All DEFENDANTS)

105. Plaintiffs incorporate by reference each and every prior paragraph of this Complaint

as though set forth in full in this cause of action.

106. At all times material to this action, the DEFENDANTS were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling, directly and indirectly, through third parties or related entities the dietary supplement Jack3d, which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiff-Decedent.

107. At all times material to this action, Jack3d was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the respective DEFENDANTS in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. it contained warnings insufficient to alert consumers, including Plaintiff-Decedent herein, of the dangerous risks and reactions associated with Jack3d, and the comparative severity, duration and the extent of the risks and reactions;

b. it contained warnings insufficient to alert consumers, including Plaintiff-Decedent herein, of the propensity to cause a substantial increased risk of serious bodily harm;

c. it contained warnings insufficient to alert consumers, including Plaintiff-Decedent herein, of the dangerous drug-drug interactions and food-drug interactions; and

d. The warnings that were given by the DEFENDANTS were not accurate, clear, and/or were ambiguous.

108. Plaintiff-Decedent could not have discovered any defect in Jack3d through the exercise of reasonable care.

109. The DEFENDANTS, as manufacturers, sellers and/or distributors of Jack3d, are held to the level of knowledge of an expert in the field.

110. Plaintiff-Decedent reasonably relied on the skill, superior knowledge, and judgment of the DEFENDANTS.

111. The DEFENDANTS had a continuing duty to warn the Plaintiff-Decedent of the dangers associated with the use of Jack3d.

112. Plaintiff-Decedent consumed and used Jack3d for its intended purpose as a dietary workout supplement.

113. Had Plaintiff-Decedent received adequate warnings regarding the risks of Jack3d, Plaintiff-Decedent would not have used it.

114. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of Jack3d, Plaintiffs suffered injuries as set forth above.

COUNT IV

BREACH OF EXPRESS WARRANTY

(Against USP DEFENDANTS and DOES 1-500)

115. Plaintiffs incorporate by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

116. At all times, USP expressly warranted that Jack3d was safe, effective and fit for use by consumers and users, including Plaintiff-Decedent, for its intended use, that it was of merchantable quality, that it did not produce dangerous side effects, that it was made from natural ingredients (i.e. geranium), and that it was adequately tested and fit for its intended purpose. Specifically, in reference to research funded by USP, USP represented on its website and through its advertising that:

a. "The hemodynamic response to acute ingestion was assessed as well. OxyElite Pro did not result in a statistically significant change in heart rate or diastolic pressure, but did cause a statistically significant change in systolic blood pressure from baseline. This increase was mild and transient, and was similar to the changes reported in the scientific literature for subjects ingesting an amount of caffeine equivalent to 2-3 cups of coffee."

b. "Jack3d, which contains DMAA, was well tolerated and no serious adverse events were noted."

c. "At the beginning and end of the study, blood pressure, heart rate and various indicators of renal and liver function were assessed. The study found that there were

no statistically significant changes from baseline to the end of the study. No serious adverse events were noted."

d. "NEWLY RELEASED, GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS' DMAA SUPPLEMENTS ARE SAFE AND EFFECTIVE."

117. At the time of making these and other warranties with respect to the safety, efficacy, testing and characteristics of Jack3d, USP knew or should have known that despite the above and other warranties alleged herein:

a. In fact, the studies cited found statistically increased blood pressure, myocardial work and RPP;

b. That participants in the studies did experience adverse cardiovascular effects from use of products even if not serious;

c. USP's studies, given their underpowered size, did not and could not prove that Jack3d does not result in serious adverse events;

d. USP's claims of safety and efficacy were not supported by researchers at the University of Memphis even though said researchers were financially interested and biased researchers;

e. Jack3d contained DMAA, which was synthetically derived, and not natural;

f. that geranium plants and oil do not contain detectable amounts of DMAA and therefore synthetic DMAA cannot be equivalent to geranium; and that

g. Since USP knew FDA had received 42 serious adverse events from DMAA products, Jack3d containing DMAA was unsafe.

118. At the time of making these warranties and other similar warranties, USP knew or should have known that, in fact, even apart from the result of USP funded studies the representations and warranties were false, misleading, and untrue in that Jack3d was not safe, effective and fit for use by consumers and users, including Plaintiff-Decedent, for its intended use, that it was not of

merchantable quality, that it did produce dangerous side effects, and that it was not adequately tested or fit for its intended purpose.

119. Plaintiff-Decedent reasonably relied upon the skill and judgment of USP, and upon said express warranties in using Jack3d. As a result, Plaintiff-Decedent used Jack3d for its intended purpose.

120. USP breached said express warranties, in that, Jack3d was not safe, effective and fit for its intended purpose, were not of merchantable quality, and, in fact, caused serious and potentially lethal side effects to consumers when taken in its recommended dose.

121. Due to USP's wrongful conduct as alleged herein, Plaintiff-Decedent could not have known about the nature of the risks and side effects associated with Jack3d until after he used it.

122. As a direct and proximate result of the USP's breach of express warranties and the unreasonably dangerous and defective characteristics of Jack3d, Plaintiffs suffered injuries as set forth above.

COUNT V

BREACH OF IMPLIED WARRANTY

(Against All DEFENDANTS)

123. Plaintiffs incorporate by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

124. At all times, DEFENDANTS impliedly warranted that Jack3d was safe, effective and fit for use by consumers and users, including Plaintiff-Decedent, for its intended use, that it was of merchantable quality, that it did not produce dangerous side effects, and that it was adequately tested and fit for its intended purpose.

125. At the time of making these warranties, DEFENDANTS knew or should have known that, in fact, the representations and warranties were false, misleading, and untrue in that Jack3d was not safe, effective and fit for use by consumers and users, including Plaintiff-Decedent, for its intended use, that it was not of merchantable quality, that it did produce dangerous side effects, and that it was not adequately tested or fit for its intended purpose.

126. Members of the public, including Plaintiff-Decedent, reasonably relied upon the skill and judgment of DEFENDANTS and upon said implied warranties in using Jack3d. As a result, Plaintiff-Decedent used Jack3d for its intended purpose.

127. DEFENDANTS breached said implied warranties, in that, Jack3d was not safe, effective and fit for its intended purpose, was not of merchantable quality, and, in fact, caused serious and potentially lethal side effects to consumers when taken in its recommended dose.

128. Due to DEFENDANTS's wrongful conduct as alleged herein, Plaintiff-Decedent could not have known about the nature of the risks and side effects associated with Jack3d until after he used it.

129. As a direct and proximate result of the DEFENDANTS' breach of implied warranties and the unreasonably dangerous and defective characteristics of Jack3d, Plaintiffs suffered injuries as set forth above.

COUNT VI

PUNITIVE DAMAGE ALLEGATIONS REGARDING SURVIVAL CLAIM

(Against USP and GNC)

130. Plaintiffs incorporate by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

131. At all times material hereto, the Defendants knew or should have known that the use of Jack3d could result in the development of serious harm and death, were ineffective and were not made from natural ingredients. Additionally, Defendants knew or should have known that the use of Jack3d would cause certain susceptible users to suffer serious injury and death, including Plaintiff-Decedent.

132. At all times material hereto, the Defendants engaged in conduct that constitutes malice, oppression or fraud, including without limitation the misrepresentations, warranties and omissions set forth above.

133. Defendants attempted to misrepresent and did misrepresent facts concerning the safety, efficacy and composition of Jack3d.

134. Defendants' misrepresentations included knowingly withholding material information from consumers and the public, including Plaintiff-Decedent, concerning the safety, efficacy and composition of Jack3d.

135. Defendants' acts of oppression, fraud or malice were on the part of corporate officers, directors or managing agents, or were on the part of employees and were ratified or authorized by USP and/or GNC.

136. Defendants continued to aggressively market Jack3d to consumers, including Plaintiff-Decedent, without disclosing the fact that use of Jack3d could result in the development of serious injuries, that it was ineffective and that it was not made from natural ingredients.

137. Defendants knew their advertising and representations were false and misleading and omitted material information, but continued to design, develop, manufacture, market, distribute, and sell Jack3d so as to maximize sales and profits.

138. Defendants intentionally concealed and/or recklessly failed to disclose to the public and Plaintiff-Decedent the potentially life threatening side effects of taking Jack3d in order to ensure continued and increased sales.

139. Defendants also downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects associated with the use of Jack3d, that Jack3d was ineffective and that Jack3d was not natural, despite available information demonstrating Jack3d was unsafe, ineffective and synthetically-created.

140. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff-Decedent of necessary information to enable Plaintiff-Decedent to weigh the true risks of Jack3d against the benefits in making his decision to use Jack3d.

141. As a direct and proximate result of the Defendant USP and GNC's conscious and deliberate disregard for the rights and safety of consumers, Plaintiff-Decedent suffered severe injury, loss and death. Plaintiffs likewise suffered loss as alleged herein. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

142. The aforesaid conduct of the Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs herein, thereby

entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT VII

WRONGFUL DEATH

(Against All Defendants)

143. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

144. As a direct and proximate result of Defendants' wrongful conduct causing the death of Plaintiff-Decedent MICHAEL L SPARLING, Plaintiffs LEANNE SPARLING and MICAEL J SPARLING suffered the loss of consortium, including the loss of love, service, society, comfort, affection, moral support, companionship, and support of the Plaintiff-Decedent.

145. As a direct and proximate result of Defendants' wrongful conduct as herein alleged and of the death of Plaintiff-Decedent MICHAEL L SPARLING, Plaintiffs LEANNE SPARLING and MICAEL J SPARLING incurred the cost of burial and funeral expenses and will lose any future financial support, gifts, benefits and value from household services that Plaintiff-Decedent would have provided.

COUNT VIII

SURVIVAL ACTION

(Against All Defendants)

146. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

147. LEANNE SPARLING and MICHAEL SPARLING are the sole heirs of the Plaintiff-Decedent MICHAEL SPARLING. Plaintiff-Decedent died intestate with no issue and no spouse. His death certificate can be found attached to Plaintiffs' Declaration pursuant to California Code of Civil Procedure 377.32 filed in this action. Plaintiff-Decedent is survived by his biological parents LEANNE SPARLING and MICHAEL SPARLING. No administration for an estate is currently pending and one has never been opened for Decedent. Nor is an administration necessary since the assets exceed the known liabilities, more than 30 days has elapsed since Decedent's death, no

petition for appointment of a personal representative is pending or has been granted, and the value of the estate assets does not exceed $50,000.

148. As a direct and proximate result of DEFENDANTS' wrongful conduct, MICHAEL L SPARLING suffered damages including pain and suffering, medical expenses, and loss of future earnings as outlined in this complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

a. As to all Counts and all DEFENDANTS, damages to the Plaintiffs in their own right and as successors in interest according to proof including as applicable:

i. Medical and care expenses of Plaintiff-Decedent according to proof;

ii. Burial and funeral expenses, according to proof;

iii. Loss of earnings (and/or profits) of Plaintiff-Decedent according to proof;

iv. Loss of future financial support, gifts, benefits and value from household services that Plaintiff-Decedent would have provided;

v. Other economic loss

b. As to all Counts and all DEFENDANTS, damages to the Plaintiffs for loss of consortium, including the loss of love, service, society, comfort, and companionship of Plaintiff-Decedent by the Plaintiffs according to proof;

c. As to all Counts and all DEFENDANTS, Awarding pre-judgment and post-judgment interest to the Plaintiff-Decedent according to proof;

d. As to all Counts and all DEFENDANTS, Awarding reasonable costs to the Plaintiffs as provided by law;

e. As to Counts VI and VIII, Awarding Plaintiffs punitive and treble damages; and

f. As to all Counts and all DEFENDANTS, Granting all such other relief as the Court deems necessary, just and proper.

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JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Date: July 15, 2014

/s/ Sean Thomas Higgins

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Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2014, I electronically filed the **FIRST AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL; AND CERTIFICATE OF SERVICE** with the Clerk of the Court using the CM/ECF System which will send notification of such filing to the e-mail addresses denoted in the Electronic Mail Notice List on Pacer.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed at Irvine, CA, this 15th day of July, 2014.

By: *s/ Sean Thomas Higgins*

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